

37. (Amended) A method for monitoring the progression of a cancer in a patient comprising the steps of:

(a) contacting a biological sample obtained from the patient with an oligonucleotide that hybridizes to SEQ ID NO:311 under moderately stringent conditions;

(b) detecting in the sample an amount of a polynucleotide that hybridizes to the oligonucleotide under moderately stringent conditions;

(c) repeating steps (a) and (b) using a biological sample obtained from the patient at a subsequent point in time; and

(d) comparing the amount of polynucleotide detected in step (c) to the amount detected in step (b) and therefrom monitoring the progression of the cancer in the patient,

wherein the moderately stringent conditions include prewashing in a solution of 5 X SSC, 0.5% SDS, 1.0 mM EDTA (pH 8.0), hybridizing at 50°C-65°C, 5 X SSC overnight; followed by washing twice at 65°C for 20 minutes with each of 2X, 0.5X and 0.2X SSC containing 0.1% SDS.

REMARKS

Favorable reconsideration of the subject application is respectfully considered in view of the above amendments and the following remarks. Following the amendments, claims 8, 9, 11, 12, 27-30 and 34-37 are under consideration.

Claims 26, 31, 32, 33, 38, 39 have been cancelled from the application. Claims 8, 9, 11 and 12 have been amended to remove reference to the cancelled claims. Claims 27-30 and 34-37 have been amended to recite specific hybridization conditions. Support for this aspect of the claims may be found on page 7, lines 19-29 to page 8, line 2 of the specification as originally filed. It is urged that support for all the above amendments may be found throughout the specification as originally filed and that none of the amendments constitute new matter or raise new issues for consideration.

The pending claims stand finally rejected under 35 USC §112, first paragraph, as lacking an adequate written description. Specifically, the Examiner continues to assert that the claims "are broadly drawn to a genus of nucleic acid molecules that encompass a larger nucleic acid." This rejection is respectfully traversed.

The pending claims are not drawn to nucleic acid molecules. Rather, the claims are drawn to methods for detecting the presence of, or monitoring the progression of, a prostate cancer in a patient, such methods comprising contacting a biological sample obtained from the patient with an oligonucleotide primer or probe that hybridizes to SEQ ID NO:67, 107, 308 or 311 under specifically recited conditions. It is not necessary for the specifically recited sequences to be full-length, or to contain an open reading frame, since the claimed methods may be successfully carried out by one of skill in the art without knowledge of the full-length sequence.

It is urged that one of skill in the art, on being provided with the instant specification, would appreciate that the applicants were indeed in possession of the claimed invention at the time the application was filed, and that the rejection of the claims under 35 USC §112, first paragraph, may thus be properly withdrawn.

The pending claims stand rejected under 35 USC §112, second paragraph, as being indefinite. Specifically, the Examiner has objected to the claims as failing to recite the specific hybridization conditions. As noted above, claims 27-30 and 34-37 have been amended to include specific hybridization conditions.

It is urged that one of skill in the art, on being provided with the instant specification, would clearly be able to determine the metes and bounds of the amended claims, and that this rejection of the claims under 35 USC §112, second paragraph, may thus be properly withdrawn.

Claims 8, 9, 11, 12, 26, 32, 33 and 39 stand finally rejected under 35 USC §102(e) as being anticipated by US Patent 5,786,148 to Bandman et al.. As noted above, independent claims 26, 32, 33 and 39 have been cancelled from the application, and claims 8, 9, 11 and 12 have been amended to remove reference to claims 26, 32, 33 and 39. Applicants respectfully submit that the rejection of the claims under 35 USC §102(e) may thus be properly withdrawn.

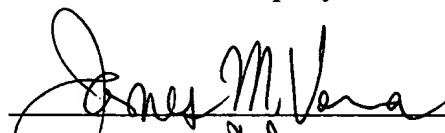
Claims 8, 9, 11, 12, 31 and 38 stand finally rejected under 35 USC §103(a) as being unpatentable over WO 98/45420. As noted above, independent claims 31 and 38 have been cancelled from the application, and claims 8, 9, 11 and 12 have been amended to remove reference to claims 31 and 38. Applicants respectfully submit that the rejection of the claims under 35 USC §103(a) may thus be properly withdrawn.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made."

Favorable reconsideration and allowance of the pending claims is respectfully requested. Should the Examiner have any further concerns regarding the subject patent application, she is respectfully requested to telephone the applicants' representative.

Respectfully submitted,

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Enclosures:

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Petition for an Extension of Time

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Version with Markings to Show Changes Made

Claims 26, 31, 32, 33, 38 and 39 have been cancelled.

Claims 8, 9, 11, 12, 27-30 and 34-37 have been amended as follows:

8. (Twice Amended) A method according to any one of claims [26-32] 27-30, wherein the amount of polynucleotide that hybridizes to the oligonucleotide is determined using polymerase chain reaction.

9. (Twice Amended) A method according to any one of claims [26-32] 27-30, wherein the amount of polynucleotide that hybridizes to the oligonucleotide is determined using a hybridization assay.

11. (Twice Amended) A method according to any one of claims [33-39] 34-37, wherein the amount of polynucleotide that hybridizes to the oligonucleotide is determined using polymerase chain reaction.

12. (Twice Amended) A method according to any one of claims [33-39] 34-37, wherein the amount of polynucleotide that hybridizes to the oligonucleotide is determined using a hybridization assay.

27. (Amended) A method for determining the presence or absence of prostate cancer in a patient, comprising the steps of:

- (a) contacting a biological sample obtained from the patient with an oligonucleotide that hybridizes to SEQ ID NO:67 under moderately stringent conditions; and
- (c) detecting in the sample an amount of a polynucleotide that hybridizes to the oligonucleotide under moderately stringent conditions, relative to a predetermined cut-off

value, and therefrom determining the presence or absence of a cancer in a patient, wherein the biological sample is selected from the group consisting of: blood, serum and semen,

wherein the moderately stringent conditions include prewashing in a solution of 5 X SSC, 0.5% SDS, 1.0 mM EDTA (pH 8.0), hybridizing at 50°C-65°C, 5 X SSC overnight; followed by washing twice at 65°C for 20 minutes with each of 2X, 0.5X and 0.2X SSC containing 0.1% SDS.

28. (Amended) A method for determining the presence or absence of prostate cancer in a patient, comprising the steps of:

- (a) contacting a biological sample obtained from the patient with an oligonucleotide that hybridizes to SEQ ID NO:107 under moderately stringent conditions; and
- (b) detecting in the sample an amount of a polynucleotide that hybridizes to the oligonucleotide under moderately stringent conditions, relative to a predetermined cut-off value, and therefrom determining the presence or absence of a cancer in a patient,

wherein the moderately stringent conditions include prewashing in a solution of 5 X SSC, 0.5% SDS, 1.0 mM EDTA (pH 8.0), hybridizing at 50°C-65°C, 5 X SSC overnight; followed by washing twice at 65°C for 20 minutes with each of 2X, 0.5X and 0.2X SSC containing 0.1% SDS.

29. (Amended) A method for determining the presence or absence of prostate cancer in a patient, comprising the steps of:

- (a) contacting a biological sample obtained from the patient with an oligonucleotide that hybridizes to SEQ ID NO:308 under moderately stringent conditions; and
- (b) detecting in the sample an amount of a polynucleotide that hybridizes to the oligonucleotide under moderately stringent conditions, relative to a predetermined cut-off value, and therefrom determining the presence or absence of a cancer in a patient, wherein the biological sample is selected from the group consisting of: blood, serum and semen,

wherein the moderately stringent conditions include prewashing in a solution of 5 X SSC, 0.5% SDS, 1.0 mM EDTA (pH 8.0), hybridizing at 50°C-65°C, 5 X SSC overnight;

followed by washing twice at 65°C for 20 minutes with each of 2X, 0.5X and 0.2X SSC containing 0.1% SDS.

30. (Amended) A method for determining the presence or absence of prostate cancer in a patient, comprising the steps of:

(a) contacting a biological sample obtained from the patient with an oligonucleotide that hybridizes to SEQ ID NO:311 under moderately stringent conditions; and

(b) detecting in the sample an amount of a polynucleotide that hybridizes to the oligonucleotide under moderately stringent conditions, relative to a predetermined cut-off value, and therefrom determining the presence or absence of a cancer in a patient,

wherein the moderately stringent conditions include prewashing in a solution of 5 X SSC, 0.5% SDS, 1.0 mM EDTA (pH 8.0), hybridizing at 50°C-65°C, 5 X SSC overnight; followed by washing twice at 65°C for 20 minutes with each of 2X, 0.5X and 0.2X SSC containing 0.1% SDS.

34. (Amended) A method for monitoring the progression of a cancer in a patient comprising the steps of:

(a) contacting a biological sample obtained from the patient with an oligonucleotide that hybridizes to SEQ ID NO:67 under moderately stringent conditions;

(b) detecting in the sample an amount of a polynucleotide that hybridizes to the oligonucleotide under moderately stringent conditions;

(c) repeating steps (a) and (b) using a biological sample obtained from the patient at a subsequent point in time; and

(d) comparing the amount of polynucleotide detected in step (c) to the amount detected in step (b) and therefrom monitoring the progression of the cancer in the patient,

wherein the biological sample is selected from the group consisting of: blood, serum and semen,

wherein the moderately stringent conditions include prewashing in a solution of 5 X SSC, 0.5% SDS, 1.0 mM EDTA (pH 8.0), hybridizing at 50°C-65°C, 5 X SSC overnight; followed by washing twice at 65°C for 20 minutes with each of 2X, 0.5X and 0.2X SSC containing 0.1% SDS.

35. (Amended) A method for monitoring the progression of a cancer in a patient comprising the steps of:

- (a) contacting a biological sample obtained from the patient with an oligonucleotide that hybridizes to SEQ ID NO:107 under moderately stringent conditions;
- (b) detecting in the sample an amount of a polynucleotide that hybridizes to the oligonucleotide under moderately stringent conditions;
- (c) repeating steps (a) and (b) using a biological sample obtained from the patient at a subsequent point in time; and
- (d) comparing the amount of polynucleotide detected in step (c) to the amount detected in step (b) and therefrom monitoring the progression of the cancer in the patient,
wherein the moderately stringent conditions include prewashing in a solution of 5 X SSC, 0.5% SDS, 1.0 mM EDTA (pH 8.0), hybridizing at 50°C-65°C, 5 X SSC overnight; followed by washing twice at 65°C for 20 minutes with each of 2X, 0.5X and 0.2X SSC containing 0.1% SDS.

36. (Amended) A method for monitoring the progression of a cancer in a patient comprising the steps of:

- (a) contacting a biological sample obtained from the patient with an oligonucleotide that hybridizes to SEQ ID NO: 308 under moderately stringent conditions;
- (b) detecting in the sample an amount of a polynucleotide that hybridizes to the oligonucleotide under moderately stringent conditions;
- (c) repeating steps (a) and (b) using a biological sample obtained from the patient at a subsequent point in time; and
- (d) comparing the amount of polynucleotide detected in step (c) to the amount detected in step (b) and therefrom monitoring the progression of the cancer in the patient,
wherein the biological sample is selected from the group consisting of: blood, serum and semen,
wherein the moderately stringent conditions include prewashing in a solution of 5 X SSC, 0.5% SDS, 1.0 mM EDTA (pH 8.0), hybridizing at 50°C-65°C, 5 X SSC overnight;

followed by washing twice at 65°C for 20 minutes with each of 2X, 0.5X and 0.2X SSC containing 0.1% SDS.

37. (Amended) A method for monitoring the progression of a cancer in a patient comprising the steps of:

(a) contacting a biological sample obtained from the patient with an oligonucleotide that hybridizes to SEQ ID NO:311 under moderately stringent conditions;

(b) detecting in the sample an amount of a polynucleotide that hybridizes to the oligonucleotide under moderately stringent conditions;

(c) repeating steps (a) and (b) using a biological sample obtained from the patient at a subsequent point in time; and

(d) comparing the amount of polynucleotide detected in step (c) to the amount detected in step (b) and therefrom monitoring the progression of the cancer in the patient,

wherein the moderately stringent conditions include prewashing in a solution of 5 X SSC, 0.5% SDS, 1.0 mM EDTA (pH 8.0), hybridizing at 50°C-65°C, 5 X SSC overnight; followed by washing twice at 65°C for 20 minutes with each of 2X, 0.5X and 0.2X SSC containing 0.1% SDS.